

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554**

In the Matter of

Revision of Part 15 of the Commission's
Rules to Permit Unlicensed National
Information Infrastructure (U-NII) Devices in
the 5 GHz Band

ET Docket No. 13-49

To: Marlene H. Dortch
Office of the Secretary, Federal Communications Commission

**Comments
Of
Association for the Advancement of Medical Instrumentation
(AAMI)**



May 24, 2013

Table of Contents

EXECUTIVE SUMMARY	iii
I. Introduction.....	2
II. Overview.....	6
III. Proposal.....	9
IV. Conclusion	12

EXECUTIVE SUMMARY

The burgeoning use of wireless applications for consumer, military and enterprise requirements is driving a rapidly increasing demand for spectrum. Nowhere is this more prevalent than in the healthcare setting where the use of wireless devices and spectrum rivals that of many military applications (e.g., naval vessels or aircraft). In addition to spectrum that had been specifically allocated to healthcare applications, the use of unlicensed spectrum for Wi-Fi and similar applications is experiencing a marked increase. Some of these applications critically affect patient and/or public safety and ideally require controlled RF environments where the spectrum utilization can be actively managed to reduce harmful interference. Therefore, AAMI applauds and supports the Commission's proposal to allocate more spectrum to Unlicensed National Information Infrastructure (U-NII) Devices in the 5 GHz Band and apply Part 15 rules for operation.

AAMI recognizes the important role that IEEE 802.11 and other wireless technologies have played in taking advantage of unlicensed spectrum and wishes to ensure these existing technologies as well as new technologies can provide access to hospital networks for medical devices. While dedicated spectrum bands should continue to be considered, these tend to have targeted uses and applications and may not always attract the focus, investment, and resulting innovations from the wireless technology providers due to the limited market opportunity. Thus, while AAMI is a strong supporter of more spectrum that can be used for healthcare applications, we believe the measures proposed in the Notice of Proposed Rulemaking may be insufficient to support the criticality of medical devices. Accordingly, AAMI proposes a secondary measure to offer a higher level of risk management and mitigation for the growing number and variety of applications in healthcare delivery organizations.

In view of the increasing expansion of wireless medical system usage and the ubiquitous nature of wireless technologies in healthcare organizations, we are requesting that the Commission adopt a mechanism that would provide to healthcare delivery organizations a healthcare vicinity-based prioritized access to a subset of the proposed expanded 5 GHz U-NII bands for the deployment of critical, interference sensitive healthcare applications. While the AAMI community itself is diverse and multi-disciplinary, the common bond that is driving AAMI to submit this proposal is *patient safety, where “mission critical” is “life critical,”* and where human beings are counting on wireless medical devices for critical life support.

This proposal was developed by a committed group of wireless experts who are part of the AAMI community and who are providing guidance to the healthcare community on increasing the awareness, knowledge, and methodologies for assuring high reliability for wireless in healthcare. The proposal was further reviewed and refined by a significant number of additional individuals from medical device companies, wireless consulting firms, healthcare delivery organizations, and other non-profit organizations with an interest in wireless.

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The Association for the Advancement of Medical Instrumentation (“AAMI”) is pleased to offer the Commission its views on the above-captioned proceeding to make additional spectrum available in the Unlicensed National Information Infrastructure (U-NII) in the 5 GHz band.¹

¹ FCC 13-22, 28 FCC Red 1769, released February 20, 2013 (NPRM).

I. Introduction

AAMI is a nonprofit organization founded in 1967. It is a diverse community of nearly 7,000 healthcare technology professionals united by one important mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology. AAMI is a primary resource for industry, healthcare delivery organizations, technology-oriented professionals, subject experts, and government for national and international standards on medical technology. AAMI also provides multidisciplinary leadership and programs that enhance the ability of the professions, healthcare delivery organizations, and industry to understand, develop, manage, and use medical technologies safely and effectively. AAMI provides a unique and critical forum for its community, from clinical and biomedical engineers and technicians, physicians, nurses, and hospital administrators, to educators and researchers, manufacturers, distributors, government representatives and other healthcare professionals with an interest in medical devices. These diverse groups have been instrumental in making AAMI the leading source of essential information on medical devices and equipment.

AAMI is not an advocacy organization for any profession, industry, or market sector. It is a neutral organization, with a uniquely multi-disciplinary community. This proposal was developed collaboratively by a number of organizations and individual experts who participate in AAMI's standards committees, task forces, or other knowledge-development groups and have a particularly high interest in and expertise around wireless issues in healthcare delivery organizations.

The burgeoning use of wireless applications for consumer, military and enterprise requirements is driving an explosive demand for wireless spectrum. Nowhere is this more

prevalent than in the healthcare setting where the use of wireless devices and spectrum rivals that of many military applications (e.g., naval vessels or aircraft). In addition to spectrum that has been allocated to healthcare applications, the use of unlicensed spectrum for Wi-Fi and similar technologies is experiencing a marked increase. According to a February 2011 white paper published by the Wi-Fi Alliance^{®2}:

“The number of Wi-Fi CERTIFIED devices in hospitals is growing significantly as the advantages of networking between devices, applications, clinicians and systems are realized. Wi-Fi communication may be present on a hospital floor in everything from infusion pumps and sensors to PCs, patient monitors, smartphones and wearable wireless devices (WWDs). As hospitals make greater use of electronic medical records (EMRs), more and more devices that interact with these records will find their way onto hospital Wi-Fi networks.”

“More than 500,000 Wi-Fi infrastructure endpoints, or access points (APs), were deployed in U.S. healthcare facilities in 2010, representing a 50 percent increase from 2009. Worldwide sales of Wi-Fi technology into the healthcare market are expected to reach \$4.9 billion in 2014.”

“Along with this device growth, the adoption of EMRs is rapidly increasing and more hospital systems are integrating clinical and information systems where data flows across the hospital network. Today 30 percent of U.S. hospitals have data electronically extracted for an electronic health record (EHR)/EMR and interfaced into an electronic file.”

In addition ABI Research predicts that the demand for MBANS devices will grow substantially³:

“The market for disposable wireless Medical Body Area Network (MBAN) sensors within professional healthcare is in its earliest stages, but key foundations to support adoption are now in place. There is also tremendous potential for adoption. So much so that by 2018, close to 5 million disposable sensors will be shipped even though MBAN sensors will have still barely penetrated the addressable market.”

These studies and reports are among several that highlight the increasing demand for (and on) wireless spectrum for healthcare applications.

² “Wi-Fi[®] in Healthcare: The solution for growing hospital communication needs”, Wi-Fi Alliance, February 2011. (<http://www.wi-fi.org/knowledge-center/white-papers/wi-fi%C2%AE-healthcare-solution-growing-hospital-communication-needs-2011>).

³ ABI Research, May 2013.

The Commission notes that, “In recent years, there has been an industry-wide push to increase the amount of spectrum available for unlicensed use.”⁴ AAMI agrees with the Commission that there is a pressing need to allocate additional unlicensed spectrum to wireless applications. There is also a growing concern for the need to support access to spectrum for critical, interference-sensitive applications in a way that allows healthcare delivery organizations the ability to control the level of congestion and interference received from unmanaged sources in their immediate vicinity.

While the AAMI community itself is diverse and multi-disciplinary, the common bond that is driving AAMI to submit this proposal is *patient safety*, where “*mission critical*” is “*life critical*,” and where human beings are counting on wireless medical devices for critical life support.

As indicated above, the wide-spread availability of off-the-shelf components and radio solutions for unlicensed bands has led to a significant increase in the use of wireless connectivity for healthcare to meet the needs of clinical workflows and meaningful use. Many of these applications depend on the wireless network for real-time remote patient surveillance and connectivity between clinical systems and operate 24/7/365. These systems require a constant connection while the lack of interference protection mechanisms in unlicensed spectrum⁵ may increase the level of risk⁶. As the 2.4 GHz ISM band becomes over-subscribed, medical applications are moving into the 5 GHz U-NII bands. However this spectrum may also become congested, which could increase the challenge of ensuring safe and effective operation and risk

⁴ NPRM at ¶ 11.

⁵ AAMI notes that there is an exception to the protection of unlicensed devices from interference with other unlicensed devices as evidenced in the protection of unlicensed wireless microphones in TV spectrum against TV White Space devices where certain unlicensed wireless microphones are able to register in TVWS databases and enjoy interference protection.

⁶ Reference ANSI/AAMI/IEC 80001-2-3:2012

management. A risk control measure to reduce the risk of a failed connection would be the allocation of “controlled interference” environments in order to operate effectively – an environment which provides a higher level of deterministic access, controlled utilization and managed co-existence.

In healthcare, critical applications support the mobility of patients and care-givers using wireless to communicate critical data, events and supporting clinical information sharing among devices and clinicians. When these applications fail due to “uncontrolled interference,” such failures can endanger patient safety. While the FCC originally allocated 14 MHz of spectrum for medical patient telemetry device uses in the Wireless Medical Telemetry Service (“WMTS”) bands, these bands are experiencing increasing use as the number of wireless medical devices that require controlled interference spectrum for safe and effective patient care has steadily increased.

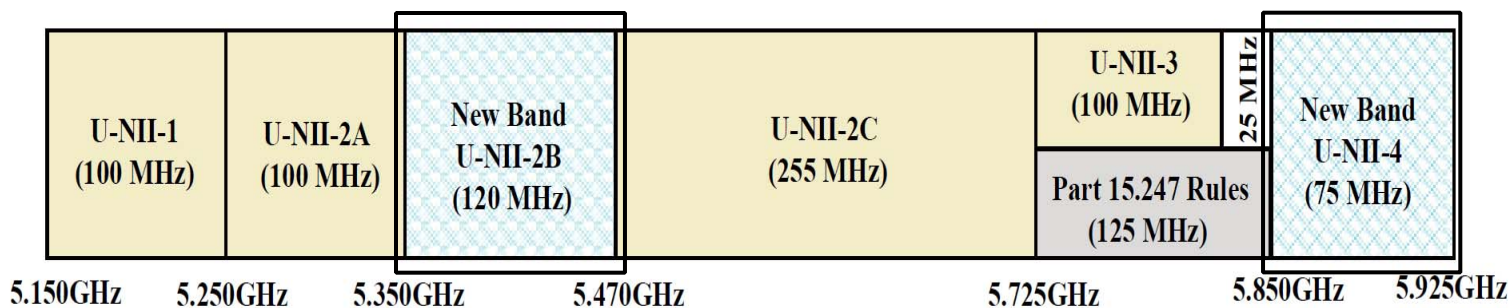
The FCC also recently allocated 40 MHz of spectrum on a secondary basis to the Medical Body Area Network Service (MBANS). The MBANS service rules appropriately limit its use to low-power wideband body-worn sensor and hub devices and not for general medical device communications. The MBANS, however, provides an example of a possible interference management approach.

The FCC’s current investigation of whether to expand the amount of spectrum available for use in the 5 GHz band by permitting unlicensed use in the U-NII-2B and U-NII-4 bands presents a unique opportunity to provide a “safe haven” for critical, interference sensitive healthcare applications. Accordingly, AAMI proposes that in expanding unlicensed use of the 5 GHz band the Commission permit healthcare facilities to have “prioritized access” in the geographical vicinity of healthcare facilities to either the U-NII-2B (5.35 – 5.47 GHz) or U-NII-4 (5.85 – 5.925 GHz) band spectrum as shown below in Figure 1. This same locally prioritized

access could also be made available to other industrial users that, like healthcare facilities, also have a need to use the spectrum for critical applications that require a “controlled interference” environment. This could be managed through the use of a geo-location database similar to TV White Space or via any of the other mechanisms proposed by the FCC in the NPRM.

Proposed U-NII Band Options For Priority Healthcare

Figure 1: Band Options for Healthcare Use



Providing a mechanism that allows for healthcare prioritized access to spectrum could support the safer development of new and innovative solutions for the care of patients, as well as for other applications in industries that require managed spectrum without permanently allocating such spectrum for specific needs.

II. Overview

AAMI believes that healthcare prioritized access to this spectrum will help to advance the use of medical devices in unlicensed spectrum and promote coexistence with existing technologies such as IEEE 802.11, thus lowering the risk of compromising patient safety. We believe this is critical to the meeting the needs of healthcare delivery organizations in terms of clinical systems and providing a safe and effective environment for patient care. Our reasons for requesting healthcare prioritized access include:

1. Healthcare providers have increasingly expanded wireless monitoring for patients from exclusively high acuity patients to the full range of patient health to a) reduce the burden of care on a limited healthcare staff and b) increase the likelihood of capturing early degradation of patient health. This evolution of healthcare has resulted in a significant increase in the number of medical devices connected to the hospital network and also the requirement for additional bandwidth per device as multiple clinical applications may exist on a single device. Future medical applications will require even more bandwidth. Examples include new physiological parameters not traditionally measured, increased time resolution and volume of reported measured parameters and waveforms as well as increasingly interactive patient care using voice and high resolution video technology.
2. Recent actions by the FCC (as directed by Congress) to possibly relocate the 608 – 614 MHz WMTS band have raised a level of uncertainty over use of this spectrum. Hospital organizations and medical device manufacturers are increasingly concerned about the long-term availability of this portion of the WMTS spectrum and the impact a reallocation would have on greater than \$2B worth of installations over the past decade.⁷
3. The FCC has been considering allocating 100 MHz of dedicated spectrum in the 3.5 GHz band for the use of medical applications and devices.⁸ Although initially this seems like an attractive proposal, it could lead to the issues outlined below:

a. Medical applications do not generally, by themselves, have the volumes that

⁷ See, “Expanding the Economic and Innovation Opportunities of Spectrum through Incentive Auctions”, GN Docket No. 12-268, Comments of the WMTS Coalition at footnote 27.

⁸ “Amendment of the Commission’s Rules with Regard to Commercial Operations in the 3550- 3650 MHz Band, FCC 12-148, 27 FCC Red 15594, released December 12, 2012.

can attract the investment needed to develop low-cost, state-of-the-art solutions, and the 3.5GHz band will not likely be an exception.

- b.** Coexistence and interoperability will require new standards development to enable safe and effective use for a high volume of devices which is also unlikely as it may not share the cost savings of commercialized technologies such as IEEE 802.11.
- c.** It may take many years to see the commercial availability of devices in this band, which places it beyond the realm of near-term consideration.⁹

- 4.** The 4.9 GHz band has seen increased use by public safety interests, but it has not been adopted broadly for healthcare use as proposed herein due to the limited bandwidth, the lack of available equipment, the coordination and licensing requirements, and the broad use by non-healthcare entities.

In light of items 1-4 above, medical equipment vendors are adding medical device capability in the 2.4 GHz and 5 GHz unlicensed bands, where commercial components are available and technology experts in healthcare delivery organizations feel comfortable. This approach results in additional challenges, such as:

- 1.** Increasing inability to safely manage Medical and IT infrastructure due to interference from other users of the spectrum, including devices brought into the facility by patients, visitors or staff and/or residential and business users on the same channels in the geographical vicinity.

⁹ We look to the TV White Space proceeding as an example where the time between the initial NPRM (May 13, 2004) and the first type-accepted device (December 22, 2011) was over six years.

2. Sharing of bandwidth and spectrum with other applications and users, with little ability to reserve bandwidth or spectrum for critical applications.
3. A quickly increasing number of devices using these bands, which will absorb any available spectrum and reduce the ability of the hospital technology staff to manage it.

Ultra-high bandwidth technologies such as IEEE 802.11ac require complex legacy compatibilities that may be perceived by hospitals as “inconvenienced” by medical devices despite their clinical nature. Future uses of the proposed U-NII band are very hard to predict at this point, but they point to an increasing mobility and a reduced ability for institutions to manage the spectrum use in their own facilities.

As a result AAMI proposes that the Commission support a plan that would allow healthcare prioritized access to channels in the proposed expanded 5 GHz band. The significant amount of proposed unlicensed spectrum available for ultra-high bandwidth applications allows for vicinity-based prioritization and use of a relatively small subset of spectrum for safe and effective operation of medical devices.

III. Proposal

In the unlicensed bands, no interference protection or coordination of use has been traditionally provided. Consequently, as use of the bands has increased, interference has been a growing problem in the 2.4 GHz band and there is concern that this will also occur in the 5 GHz band. To make new spectrum available on the same basis may simply extend the same problems arising as the new bands become popular and crowded. We therefore recommend that a subset of the new bands be made available with service rules that allow healthcare prioritized access.

Service rules could be created that will allow prioritized access for healthcare use and perhaps critical facilities in other sectors.

We urge the Commission to establish a mechanism that allows healthcare institutions, who require “controlled interference” spectrum in a small portion of the proposed bands, healthcare prioritized access to the proposed new portions of the 5 GHz ISM band similar or analogous to the current protection afforded to TVWS systems. This spectrum, which can be used for “controlled interference” life-critical or other critical infrastructure wireless applications, with access to commercial, off-the-shelf technology, would:

1. Allow the re-use of commercial solutions which would lower the cost of development and implementation of safe solutions for life-critical patient care applications.
2. Allow access to state-of-the-art technology, supporting improved spectral efficiency, more contiguous spectrum, and vastly higher data rates, thereby enabling innovation.
3. Provide enough bandwidth for ultra-high bandwidth devices using technology such as IEEE 802.11ac while providing the opportunity for a high bandwidth “controlled interference” environment for medical devices in institutions that desire to take advantage of this capability.

We believe that healthcare prioritized access to spectrum in the geographical vicinity of registered critical users is both a much needed and practical solution. Since the Commission is proposing to increase the size of the 5 GHz band with an additional 195 MHz of spectrum, this would provide additional spectrum for users of compatible technologies.

Specifically we are requesting that:

1. A mechanism be created (similar perhaps to TV White Space) that allows a

healthcare institution to gain vicinity-based prioritized access to either the U-NII-2B or U-NII-4 band in the proposed new 5 GHz spectrum.

2. All users within a specified distance from the prioritized institution would be prohibited from using this spectrum according to the local priorities for use.
3. We propose that whichever mechanism is chosen for coordination of this new spectrum in the 5 GHz band with incumbent users also be used for coordination with prioritized users. The options proposed in the NPRM are:¹⁰
 - Geo-location based technology
 - Sensing based technology
 - Beaconsing / pilot channel technology

While this proposal may somewhat limit access by the public to these channels, this is only under very restricted circumstances and within a very restricted geographic area of a healthcare delivery organization and still affords a significant amount of bandwidth for public consumption. Only users that are located within close proximity of a hospital or facility with critical interference sensitive applications may be affected. We have estimated that this could affect <0.05% of the US population.¹¹ However, these protection mechanisms would provide the very significant public benefit of limiting interference in critical infrastructure areas, such as hospitals, clinics, and near first responder command centers.

¹⁰NPRM for example at ¶21 and ¶105.

¹¹ The average footprint of a US hospital is 55,000 square feet (<http://www.aep.uci.edu/der/buildingintegration/2/BuildingTemplates/Hospital.aspx>) (235 x 235 sq. ft.), whereas medical centers tend to have a larger footprint of 200,000+ square feet (450 x 450 sq. ft.) which is extended to 425,000 sq. ft. when the wireless range of 200 ft. is added. Assuming that urban hospitals would be the primary users of this capability, they are typically located in areas that have population densities greater than 10,000 people per square mile (http://en.wikipedia.org/wiki/List_of_United_States_cities_by_population_density). Assuming 1,000 (out of 6411 in the US) hospitals, a 225,000 sq. ft. external wireless exclusion zone and 20,000 people per square mile, then this proposal would affect 160,000 people or ~0.05% of the US population.

IV. Conclusion

The use of wireless devices in a healthcare setting has increased and is continuing to increase at a rapid pace. While useful for specific situations, the spectrum currently dedicated for healthcare applications is either heavily used or does not lend itself to wide-spread healthcare medical device or IT uses. Allowing healthcare vicinity-based priority access to one of the five GHz U-NII bands under discussion will provide much-needed spectrum for medical devices to operate in a managed interference environment. We believe this will foster and support innovative technology solutions leading to improved patient outcomes.

Again, while the AAMI community itself is diverse and multi-disciplinary, the common bond that is driving AAMI to submit this proposal is *patient safety*.

We thank the Commission for this opportunity to provide our views on this issue and look forward to further communications with on this important topic.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mary Logan", with a stylized flourish extending to the right.

Ms. Mary K. Logan, JD, CAE
President
Association for the Advancement of
Medical Instrumentation

May 24, 2013